

67. The isolated protein of claim 66 wherein the signal transduction is mediated by

IL-6.

REMARKS

In the Office Action dated October 9, 2001, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the pending claims, i.e., claims 6-12 and 41-51, represents multiple separate and distinct inventions, allegedly because different SOCS molecules differ in structure and in function. The Examiner requests Applicants to draft the specific invention for examination as follows:

In claims 6 and 10, specify each "Xaa" variable of SEQ ID NO: 51. The Examiner indicates that Applicants may elect sequences that correspond to the mouse (and rat) and human homolog of a SOCS member.

In claims 42 and 43, elect two SOCS box sequences found in the mouse (and rat) or human homolog sequences elected by Applicants in claims 6 and 41.

In claims 45 and 46, elect two protein sequences found in the mouse or human homolog sequences elected by Applicants in claims 6 and 41.

In Claims 47, 48 and 49, elect three nucleic acid sequences found in the mouse, rat, or human homolog sequences elected by Applicants in claims 6 and 41.

The Examiner further indicates that, considering the burden of this second restriction on Applicants, claims to nucleic acid molecules and to proteins would both be included in the examination.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter relating to SOCS1, which is more clearly delineated in added claims 52-67. Specifically, Claims 52-61 are directed to SOCS1 nucleic acid molecules, homologs thereof, expression vectors and host cells. Claims 62-67 are directed to SOCS1 proteins and homologs thereof. SEQ ID NO: 52 recited in the claims

represents the sequence of the SOCS box from mouse and rat SOCS1. SEQ ID NO: 55 represents the sequence of the SOCS box from human SOCS1. SEQ ID NO: 4, SEQ ID NO: 10 and SEQ ID NO: 12 represent the protein sequences of SOCS1 from mouse, human and rat, respectively. SEQ ID NO: 3, SEQ ID NO: 9 and SEQ ID NO: 11 represent the nucleotide sequence of SOCS1 from mouse, human and rat, respectively.

It is respectfully submitted that added claims 52-67 are fully supported by the present specification and by pending claims 6-12 and 41-52, and are consistent with the Examiner's recommendations in the pending Office Action. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the present case, the molecules of the SOCS family are related to each in both structure and function. With respect to the structure, all the SOCS proteins share a conserved

SOCS box motif as defined in SEQ ID NO: 51. With respect to the function, all the SOCS proteins have the capacity of modulating signal transduction. Thus, the molecules of the SOCS family are clearly related to each other and are merely different aspects of the present invention.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal

challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of different SOCS molecules as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



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FSD/XZ:ab
Enc. Version with Markings to Show Changes Made

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please add the following claims:

52. An isolated nucleic acid molecule encoding a protein which comprises a SOCS box, wherein said SOCS box comprises an amino acid sequence as set forth in SEQ ID NO: 52 or SEQ ID NO: 55, or an amino acid sequence having at least about 70% similarity to SEQ ID NO: 52 or SEQ ID NO: 55.

53. The isolated nucleic acid molecule of claim 52, wherein said protein comprises an amino acid sequence as set forth in any one of SEQ ID NO: 4, SEQ ID NO: 10 or SEQ ID NO: 12, or an amino acid sequence having at least about 50% similarity to any one of SEQ ID NO: 4, SEQ ID NO: 10 or SEQ ID NO: 12.

54. An isolated nucleic acid molecule comprising a nucleotide sequence as set forth in any one of SEQ ID NO: 3, SEQ ID NO: 9 or SEQ ID NO: 11, or a nucleotide sequence which hybridizes under low stringency conditions to any one of SEQ ID NO: 3, SEQ ID NO: 9 or SEQ ID NO: 11, wherein said low stringency conditions comprise at least about 1% v/v to at least about 15% v/v formamide at least about 1M to about 2M salt for hybridization at 42°C, and at least about 1M to about 2M salt for washing.

55. The isolated nucleic acid molecule of any one of claims 52-54, wherein said nucleic acid molecule is derived from mouse, rat or human.

56. The isolated nucleic acid molecule of any one of claims 52-54, wherein said protein modulates signal transduction.

57. The isolated nucleic acid molecule according to claim 56, wherein said protein modulates cytokine-mediated signal transduction.

58. The isolated nucleic acid molecule according to claim 57 wherein the signal transduction is mediated by IL-6.

59. An expression vector comprising the nucleic acid molecule of any one of claims 52-54.

60. A host cell comprising the expression vector of claim 59.

61. A method of producing a SOCS protein, said method comprising culturing the host cell of claim 60 under conditions allowing the expression of said SOCS protein, and isolating said SOCS protein.

62. An isolated protein comprising a SOCS box, wherein said SOCS box comprises an amino acid sequence as set forth in SEQ ID NO: 52 or SEQ ID NO: 55, or an amino acid sequence having at least about 70% similarity to SEQ ID NO: 52 or SEQ ID NO: 55.

63. An isolated protein comprising an amino acid sequence as set forth in any one of SEQ ID NO: 4, SEQ ID NO: 10 or SEQ ID NO: 12, or an amino acid sequence having at least about 50% similarity to any one of SEQ ID NO: 4, SEQ ID NO: 10 or SEQ ID NO: 12.

64. The isolated protein of claim 62 or 63, wherein said protein is derived from mouse, rat or human.

65. The isolated protein of claim 62 or 63, wherein said protein modulates signal transduction.

66. The isolated protein of claim 65, wherein said protein modulates cytokine-mediated signal transduction.

67. The isolated protein of claim 66 wherein the signal transduction is mediated by

IL-6.